

AUSTALIAN GOLD SENSITIVE SUN PROTECTION SPF 50- avobenzone, homosalate, octisalate, octocrylene lotion
Prime Enterprises Inc.

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Australian Gold Little Joey Sensitive Sun Protection SPF 50 (non-Kakadu)

Active Ingredients

Avobenzone 3%

Homosalate 10%

Octocrylene 5%

Octisalate 5%

Purpose

Sunscreen

Uses

- helps prevent sunburn
 - if used as directed with other sun protection measures (see **Directions**) decreases the risk of skin cancer and early skin aging caused by the sun

Warnings

For external use only

Do not use on damaged or broken skin

When using this product keep out of eyes. Rinse with water to remove.

Stop use and ask a doctor if rash occurs

Keep out of reach of children. If product is swallowed, get medical help or contact a Poison Control Center right away.

Directions

- apply liberally 15 minutes before sun exposure and rub into skin
- reapply:
 - after 80 minutes of swimming or sweating
 - immediately after towel drying
 - at least every 2 hours

- **Sun Protection Measures** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF value of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10am-2pm
 - wear long sleeve shirts, pants, hats, and sunglasses
 - children under 6 months: Ask a doctor

INACTIVE INGREDIENTS

Water, Aloe Barbadensis Leaf Juice, Glycerin, Polyethylene, C12-15 Alkyl Benzoate, Phenoxyethanol, Polysorbate 20, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Sodium Hydroxide, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Propylene Glycol, Camellia Sinensis (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride

Other Information

- Protect this product from excessive heat and direct sun
- May stain some fabrics or surfaces

Questions or Comments?

Call Toll free 1-855-LIV-GOLD (548-4653)

Australian Gold Little Joey Sensitive Sun Protection SPF 50



LITTLE JOEY

by

Australian Gold

SENSITIVE
SUN PROTECTION

HYPOALLERGENIC
FRAGRANCE FREE
VEGAN & CRUELTY FREE

50

LOTION SUNSCREEN

PEDIATRICIAN TESTED

WATER RESISTANT
(80 MINUTES)

BROAD SPECTRUM SPF 50

8 FL OZ (237 mL)

Australian Gold

Little Joey SPF 50 Lotion

Little Joey by Australian Gold is a line of specially formulated products with little ones in mind. All of the ingredients are carefully selected and pass top safety standards, so you can feel confident in your choice of protection!

- Oxybenzone Free
- Cruelty Free
- Hypoallergenic
- Octinoxate Free
- Gluten Free
- Fragrance Free
- Vegan
- Phthalate Free
- Quick Dry Formula

Drug Facts

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 - after 80 minutes of swimming or sweating
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- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a broad spectrum SPF of 15 or higher and other sun protection measures including:
 - limit time in the sun, especially from 10 a.m. – 2 p.m.
 - wear long-sleeve shirts, pants, hats and sunglasses
 - children under 6 months: Ask a doctor

Inactive Ingredients:

Water, Aloe Barbadosensis Leaf Juice, Glycerin, Polyethylene, C12-15 Alkyl Benzoate, Phenoxyethanol, Polysorbate 20, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Carbomer, Sodium Hydroxide, Helianthus Annuus (Sunflower) Seed Oil, Olea Europaea (Olive) Fruit Oil, Sorbitan Oleate, Theobroma Cacao (Cocoa) Seed Butter, Tocopheryl Acetate, Hydroxypropyl Methylcellulose, Ethylhexylglycerin, Tetrasodium Glutamate Diacetate, Propylene Glycol, Camellia Sinensis (Green Tea) Leaf Extract, Melaleuca Alternifolia (Tea Tree) Leaf Oil, Sodium Chloride

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www.AustralianGold.com



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AUSTALIAN GOLD SENSITIVE SUN PROTECTION SPF 50

avobenzone, homosalate, octisalate, octocrylene lotion

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58443-0618
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
AVOBENZONE (UNII: G63QQF2NOX) (AVOBENZONE - UNII:G63QQF2NOX)	AVOBENZONE	29.58 mg in 1 mL
HOMOSALATE (UNII: V06SV4M95S) (HOMOSALATE - UNII:V06SV4M95S)	HOMOSALATE	98.6 mg in 1 mL
OCTISALATE (UNII: 4X49Y0596W) (OCTISALATE - UNII:4X49Y0596W)	OCTISALATE	49.3 mg in 1 mL
OCTOCRYLENE (UNII: 5A68WGF6WM) (OCTOCRYLENE - UNII:5A68WGF6WM)	OCTOCRYLENE	49.3 mg in 1 mL

Inactive Ingredients

Ingredient Name	Strength
CARBOMER COPOLYMER TYPE A (UNII: 71DD5V995L)	
ALOE VERA LEAF (UNII: ZY81Z83H0X)	
GREEN TEA LEAF (UNII: W2ZU1RY8B0)	
SUNFLOWER OIL (UNII: 3W1JG795YI)	
.ALPHA.-TOCOPHEROL ACETATE (UNII: 9E8X80D2L0)	
GLYCERIN (UNII: PDC6A3C0OX)	
ALKYL (C12-15) BENZOATE (UNII: A9EJ3J61HQ)	
SORBITAN MONOOLEATE (UNII: 06XEA2VD56)	
PHENOXYETHANOL (UNII: HIE492ZZ3T)	
POLYSORBATE 20 (UNII: 7T1F30V5YH)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	
COCOA BUTTER (UNII: 512OYT1CRR)	
TETRASODIUM GLUTAMATE DIACETATE (UNII: 5EHL50I4MY)	
HIGH DENSITY POLYETHYLENE (UNII: UG00KM4WR7)	
CARBOMER HOMOPOLYMER, UNSPECIFIED TYPE (UNII: 0A5MM307FC)	
ETHYLHEXYLGLYCERIN (UNII: 147D247K3P)	
HYPROMELLOSES (UNII: 3NXW29V3WO)	
TEA TREE OIL (UNII: VIF565UC2G)	
OLIVE OIL (UNII: 6UYK2W1W1E)	
PROPYLENE GLYCOL (UNII: 6DC9Q167V3)	
WATER (UNII: 059QF0K00R)	
SODIUM CHLORIDE (UNII: 451W47IQ8X)	

Product Characteristics

Color	white (White)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:58443-0618-4	237 mL in 1 BOTTLE; Type 0: Not a Combination Product	02/04/2020	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	M020	02/04/2020	

Labeler - Prime Enterprises Inc. (101946028)

Registrant - Prime Enterprises Inc. (101946028)

Establishment

Name	Address	ID/FEI	Business Operations
Prime Enterprises Inc.		101946028	pack(58443-0618) , manufacture(58443-0618) , label(58443-0618) , analysis(58443-0618)

Revised: 3/2023

Prime Enterprises Inc.